K013484

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510(k) Summary of Safety and Effectiveness

Statement

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR §807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

Device description

The *Telstar™ Magnetic Navigation System* [MNS] is an interventional workstation for the intravascular navigation of a magnetic device through tissue to designated target sites in the heart and coronary vasculature. It combines a bi-planar fluoroscopy system with a computer controlled magnetic field generator, to provide both visualization and control of a magnetically actuated catheter. The system employs magnetic fields to *orient* the catheter.

The *Telstar™* Bi-plane Imaging System [TIS] is a digital fluoroscopic system providing bi-plane fluoroscopic clinical images of both patients and medical devices during conventional and magnetic procedures.

The Niobe™ EP Catheter is a conventional 5-8F mapping catheter modified to accommodate magnetic actuation and control. It is designed to navigate into the right heart in order to measure and record electrical activity, and to pace the heart. A separate two-conductor junction box cord is supplied to allow electrical signals to be transmitted from the sterile catheter to a non-sterile signal recorder junction box.

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510(k) Summary of Safety and Effectiveness, Continued

Intended use

Magnetic Navigation System: The MNS is intended to navigate a magnetic device through tissue to designated target sites in the right and left heart and coronary vasculature by orienting the device tip in a desired direction.

Telstar Bi-plane Imaging System: Provides the utility of fluoroscopic imaging of vascular systems for applications including vascular angiography and electrophysiology (EP) studies. This x-ray system may be used stand-alone, or in conjunction with an associated Stereotaxis Magnetic Navigation System.

Niobe EP Catheter: The EP Catheter is intended for intracardiac electrophysiological recording and/or stimulation for pacing in the right heart.

Substantial equivalence

The MNS, TIS, and Niobe Catheter are substantially equivalent to the following cleared medical devices:

Stereotaxis Device	Predicate Device	Predicate 510(k) No.
MNS	Catheter Research CRI Electronic Control System	K924125
Telstar Bi-plane Imaging System	OEC Medical Systems IMDIS	K974355
Niobe Catheter	EP Technologies Steerocath	K900765

Technological characteristics

The Magnetic Navigation System employs application of magnetic fields to orient the distal tip of a magnetically actuated catheter. The TIS provides visualization through standard fluoroscopy. The Niobe Catheter is an electrophysiology mapping catheter designed to accommodate magnetic actuation and control.

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510(k) Summary of Safety and Effectiveness, Continued

Device comparisons – steering control

The following is a comparison of the key features of the MNS vs. the predicate device, the CRI Electronic Control System, K924125.

Device Characteristics	MNS	CRI System
Direct contact with patient tissue	No	No
Remote tableside physician control of steerable device distal orientation	Yes	Yes
Electronic/computer control of steerable device distal orientation	Yes	Yes
Conducted under fluoroscopic visualization	Yes	Yes
Automated advancement of the steerable device	No	Yes

Device comparisons – Imaging

The following is a comparison of the key features of the Telstar Bi-plane Imaging System vs. the predicate device, the OEC Medical Systems IMDIS, K974355.

Device Characteristics	Bi-plane Imaging System	OEC Medical Systems IMDIS
Imaging	Fluoroscopic	Fluoroscopic & spot-film
Mobility	No	Yes
Pulsed fluoro	7.5, 15, 30 pulses/sec	2, 4, 8, 15 pulses/sec
Pulsed cardiac	15, 30 pulses/sec	8, 15, 30 pulses/sec
X-ray tube assembly	Rotating anode	Rotating anode
Image intensifier	Yes	Yes
Monitor	Quad 15"	Dual 16"

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510(k) Summary of Safety and Effectiveness, Continued

Device comparisons – Catheters

The following is a comparison of the key features of the Niobe Catheter vs. the predicate device, the EP Technologies Steerocath, K900765.

Device Characteristics	Niobe EP Catheter	EP Technologies Steerocath
Direct patient contact	Yes	Yes
Single use	Yes	Yes
Catheter body size/length	5-8 French/130 cm	6 French/100, 130 cm
Catheter body composition	Poly Ether Block Amide (Pebax)	Nylon
Mechanism of catheter advancement/retraction	Direct physician control via physical manipulation	Direct physician control via physical manipulation
Mechanism of distal tip orientation (steering control)	Physician-determined magnetic vectors via a computer interface	Physical manipulation via a thumbwheel lever at the proximal end of the catheter
Distal tip	Contains Neodymium-Iron-Boron magnets	No magnets
Articulation wires (stylets) within catheter	No	Yes
Mechanism of steering orientation	Magnetic field-induced torque	Physically induced torque

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510(k) Summary of Safety and Effectiveness, Continued

Physical testing	Testing of the EP Catheter was performed in accordance with the FDA "Electrode Recording Catheter Preliminary Guidance" (March, 1995). The catheter met or exceeded all requirements for biocompatibility and physical characteristics. The Bi-plane X-ray System is designed and tested in compliance with the requirements of 21 CFR §1020.32 (Fluoroscopic Equipment).
Preclinical animal performance data	The MNS was used to steer the Niobe EP Catheter to designated sites within the canine heart. The ability of the Niobe EP Catheter and the predicate Steerocath to steer to the target sites was equivalent. Both the Niobe EP Catheter and Steerocath recorded clinically acceptable, comparable, intracardiac electrograms at each site.
Clinical performance data	Clinical evaluation was carried out in a single site, 20 patient study to confirm the safety and effectiveness of the MNS, TIS, and Niobe Catheter. Successful navigation of the catheter was achieved to 198 of 200 designated targets in the 20 patients. The conventional marketed catheter also employed was not able to reach the RV apex in one of the two patients. The Stereotaxis *Magnetic Navigation System*, Telstar Bi-plane Imaging System, and Niobe EP Catheter were demonstrated to be substantially equivalent to their respective predicate devices.
Contact	Peter A. Takes, Ph.D., RAC Director, Clinical & Regulatory Affairs Stereotaxis, Inc. 4041 Forest Park Avenue St. Louis, Missouri 63108 Ph. 314-615-6964 Fax 314-615-6912
Date	April 29, 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 5 2002

Peter A. Takes, Ph.D., RAC
Director
Clinical and Regulatory Affairs
Stereotaxis, Inc.
4041 Forest Park Avenue
St. Louis, Missouri 63108

Re: K013484
Trade Name: Telstar™ Magnetic Navigating System, Telstar™ Bi-plane Imaging System and Niobe™ EP Catheter
Regulation Number: 21 CFR 870.1290, 892.1650, and 870.1220
Regulation Name: Steerable Catheter Control System, Image-Intensified Fluoroscopic X-ray System, and Electrode Recording Catheter
Regulatory Class: Class II (two)
Product Code: DXX, MQB, and DRF
Dated: February 1, 2002
Received: February 4, 2002

Dear Dr. Takes:

This letter corrects our substantially equivalent letter of May 2, 2002, regarding the 510(k) number written in the Indications for Use Statement. That number was erroneously written as K01384 although it should have been K013484. Additionally, a newer product code, MQB instead of JAA, has been chosen for the Telstar™ Bi-plane Imaging System to reflect the use of solid state imagers in the device.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Statement - MNS

Indications for Use Statement:

510(k) Number: K013484

Device Name: Telstar™ Magnetic Navigation System [MNS]

Indications for Use: The MNS is intended to navigate a magnetic device through tissue to designated target sites in the right and left heart and coronary vasculature by orienting the device tip in a desired direction.

Statement – Bi-plane Imaging System

Indications for Use Statement:

510(k) Number: K013484

Device Name: Telstar™ Bi-plane Imaging System [TIS]

Indications for Use: The Telstar™ Bi-plane Imaging System provides the utility of fluoroscopic imaging of vascular systems for applications including vascular angiography and electrophysiology (EP) studies. This x-ray system may be used stand-alone, or in conjunction with an associated Stereotaxis Magnetic Navigation System

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Statement – Niobe Catheter

Indications for Use Statement:

510(k) Number: K013484

Device Name: Niobe™ EP Catheter

Indications for Use: The Niobe EP Catheter is intended for intracardiac electrophysiological recording and/or stimulation for pacing in the right heart.

Division of Cardiovascular & Respiratory Devices
510(k) Number K013484

Prescription Use: X